

Translation

PATENT COOPERATION TREATY

PCT/FR2002/003089



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference F16006/SP | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/FR2002/003089 | International filing date (<i>day/month/year</i>) 11 septembre 2002 (11.09.2002) | Priority date (<i>day/month/year</i>) 11 septembre 2001 (11.09.2001) |
| International Patent Classification (IPC) or national classification and IPC G01N 33/50 | | |
| Applicant ENDOGENICS et al. | | |

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| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u> </u> sheets.</p> | |
| <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p> | |

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|---|--|
| Date of submission of the demand 27 mars 2003 (27.03.2003) | Date of completion of this report 30 June 2003 (30.06.2003) |
| Name and mailing address of the IPEA/EP | Authorized officer |
| Facsimile No. | Telephone No. |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/FR2002/003089

I. Basis of the report

1. This report has been drawn on the basis of (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.):

☒ the international application as originally filed.

☒ the description, pages 1-54, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,
pages _____, filed with the letter of _____.

☒ the claims, Nos. 1, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. 2-11, filed with the letter of 08 April 2003 (08.04.2003),
Nos. _____, filed with the letter of _____.

☐ the drawings, sheets/fig _____, as originally filed,
sheets/fig _____, filed with the demand,
sheets/fig _____, filed with the letter of _____,
sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.

Claims 8-11, which relate to a "rechargeable software product", were not the subject of a search. Therefore, no opinion will be given on the novelty, inventive step and industrial applicability of said claims.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|-------|-----|
| Novelty (N) | Claims | 1 - 7 | YES |
| | Claims | | NO |
| Inventive step (IS) | Claims | 1 - 7 | YES |
| | Claims | | NO |
| Industrial applicability (IA) | Claims | 1 - 7 | YES |
| | Claims | | NO |

2. Citations and explanations

1. Reference is made to the following documents:

D1: EP-A-0 549 414, 30 June 1993

D2: WO 99 05523 A, 4 February 1999

D3: Patent Abstracts of Japan, vol.015, no. 044 (P-1161), 4 February 1991 & JP 02 280061 A, 16 November 1990

2. Novelty and inventive step (PCT Article 33(1), (2) and (3))

2.1 Document D1 describes a method for counting red blood cells or platelets, characterized in that the total platelet and red blood cell count is performed on a sample, a red blood cell lysing agent is added to said sample, the platelets alone are counted, and, if desired, the number of red blood cells is determined by simple subtraction (page 2, lines 18 to 21).

2.2 Document D2 discloses a method for counting the number of white blood cells, determining the hemoglobin concentration, and differentiating at least four sub-populations of leukocytes in a blood

sample. This method enables the morphology of the leukocytes and the surface markers to be preserved without using a fixative (abstract; page 4, line 23 to page 6, line 17).

2.3 Document D3 relates to a method for measuring a small amount of a sample, for example, for determining the presence of a tumor marker antigen by means of an antigen-antibody reaction.

2.4 The subject matter of the present application relates to a method for evaluating or diagnosing the *dynamic* biological condition of a patient or a healthy subject.

This method involves determining a plurality of known and referenced metabolic and/or tissue parameters, i.e. elements or substances contained in the blood, measuring a plurality of indexes (J1 to J157) using said parameters, comparing said indexes with values obtained in healthy subjects, and interpreting the results of the measurements performed.

The method according to the present invention, unlike the methods commonly used, has the advantage of providing an indication of the ways in which the parameters measured can be modified and/or maintained within the normal range, and of enabling the patient's biological condition to be monitored and a prognosis made (as demonstrated by the results shown in tables I to XXV).

None of the available prior art documents describes or suggests the determination of indexes J1 to J157 as described in step 3 of the method according to

claim 1.

The subject matter of claim 1 and claims 2-7, which are dependent thereon, can therefore be considered to be novel and to involve an inventive step.

3. **Industrial applicability** (PCT Article 33(1) and (4))

The subject matter of claims 1-7 can be considered to be industrially applicable.